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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/888,860	06/25/2001	David B. Weiner	UPN-3983	1975

7590

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EXAMINER

MARVICH, MARIA

ART UNIT PAPER NUMBER

1636

DATE MAILED: 06/14/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/888,860

Applicant(s)

WEINER ET AL.

Examiner

Maria B. Marvich

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 June 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Drawings

Formal drawings have been submitted which fail to comply with 37 CFR 1.84. Please see the enclosed form PTO-948.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 8 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Regarding claim 8, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Stratagene, 1992 catalog.

The Stratagene catalog describes a vector (pBK-CMV) comprising an SV40, F1 and ColE1 origin of replication, the following promoters- lac promoter,, a bla promoter, a CMV promoter, a T3 promoter, SV40 promoter and in the opposite orientation a T7 promoter-, a

multiple cloning site (polylinker), a SV40 poly adenylation site, neomycin (kanamycin) and G418 selectable markers (page 18-19). A separate vector is described (pPbac) comprising a F1 origin of replication, a P10 and POLH promoter in opposite orientation to one another, SmaI-BamHI cloning sites, poly-adenylation site and an ampicillin selectable markers (page 45).

Claims 1, 2, 5, 7, 9, 10, 12, 13, and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Matthey et al., (1999).

Matthey et al. describes a vector (pBMO.5) comprising a pBR322 and fl origin of replication, a T7 lac promoter, a polylinker and a kanamycin selectable marker (Figure 1, page 148). The A truncated pseudomonas exotoxin gene (ETA') was subcloned into the MCS of pBMO.5 downstream of the T7 lac promoter to produce pBMO.1. The kanamycin gene is transcribed in the opposite orientation of ETA' inherent in this is a promoter for kanamycin. As well a poly(A) signal is located at 3' end of the kanamycin coding sequence as identified in pET-27B(+) (Novagen sequence map). PBMO.1 is transfected into E.coli BL21 cells for toxin expression (page 147, column 2, line 39-43).

Claims 1, 2, 3, 4, 6, 7, 13 and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Invitrogen, 1994 catalog.

The Invitrogen catalog describes a vector (p2Bac) comprising a ColE1 origin of replication, an enhancer-promoter sequence of AcMNPV polyhedrin Ppol in the opposite orientation of a p10 promoter Pp10, multiple cloning sites (polylinker), poly adenylation sites

and ampicillin (page 41). Also provided is custom cloning and expression by Invitrogen mammalian cells will serve as a host cell for this vector (page 66).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 11 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over p2Bac (Invitrogen) in view of Bukrinsky *et al.* (Science 220 (4596) pp 515-519).

Applicants claim a vector for the amplification of the HIV-1 env gene as well as a method of amplifying a toxic gene in bacteria comprising inserting a toxic gene into the polylinker of claim 1, inserting the vector into bacteria and amplifying said vector in said bacteria.

p2Bac satisfies the requirements for the vector recited in claim 1. Invitrogen does not teach insertion of a toxic gene into said vector nor does it teach insertion of the HIV-1 env gene into p2Bac.

Bukrinsky *et al.* teach the cloning of the HIV env gene (page 416, column 2, line 9-11). A method for the transfection and amplification of said gene in E. coli LBG1081 cells is also provided (page 416, column 1, last sentence to column 2, line 5). A person of ordinary skill in the art would have been motivated to choose to clone the HIV env gene into pBK-CMV for the

purpose of amplification of the clone for the eventual expression of HIV-1 *env*. Motivation for the cloning and amplification of viral toxin genes such as HIV-1 *env* find their impetus in its use in the development of gene therapy products i.e. as part of or in association with a recombinant vaccine, attenuated vaccine or DNA vaccine or as components of gene therapy using vectors (application specification page 3, line 2-7). It would have been obvious to someone of skill in the art to utilize pBK-CMV in order to amplify the HIV-1 *env* gene due to the ability of this vector to amplify said toxin in prokaryotic and express it in eukaryotic hosts and the success of utilization of this vector in the art. Given the teachings of the cited art and the level of skill of the ordinary skilled artisan at the time of the applicant's invention, it must be considered that said ordinary skilled artisan would have had a reasonable expectation of success in practicing the claimed invention.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maria B Marvich, PhD whose telephone number is (703) 605-1207. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucell, PhD can be reached on (703) 305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the patent analyst, Kay Pinkney, whose telephone number is (703)-305-3553.



Maria B Marvich, PhD
Examiner
Art Unit 1636

June 11, 2002

DAVID GUZO
PRIMARY EXAMINER

